

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<b>Applicant:</b>	Copa et al.	<b>Examiner:</b>	Yabut, Diane D.
<b>Serial No.</b>	10/646,383	<b>Group Art Unit:</b>	3734
<b>Filed:</b>	August 21, 2003	<b>Docket No.</b>	AMS0008/US
<b>For:</b>	ANASTOMOSIS DEVICE AND RELATED METHODS		

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Daniel C. Schulte  
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**APPEAL BRIEF**

Dear Madam:

This Appeal Brief is being submitted in support of an Appeal from the Final Rejection mailed May 24, 2010, in connection with the above-identified patent application.

A Notice of Appeal was filed on September 22, 2010, with the required fee.

The two-month shortened statutory period for reply expired on November 22, 2010. A request for a one-month extension of time is made to extend the period of timely response to December 22, 2010. The fee for filing the extension and this Appeal Brief is being paid by credit card via EFS. It is respectfully submitted that this Appeal Brief is timely filed. If any additional extension period is required in order for this paper to be timely filed, then Appellants hereby request an extension for such additional time period and authorize the appropriate fees therefore to be charged to the Kagan Binder Deposit Account No. 50-1775 and notify us of the same.

It is believed that no additional fee is due. However, if any fee is due, please charge Kagan Binder Deposit Account No. 50-1775 and notify us of the same.

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**I. Real Party in Interest**

AMS Research Corporation, the assignee of record, is the real party in interest.

## **II. Related Appeals and Interferences**

1. There is a co-pending appeal, in Application No. 11/804,114, the Appeal Brief of which is filed on even date herewith. Application No. 11/804,114 claims priority to this application. No decision has yet been rendered by the Board of Patent Appeals and Interferences on the appeal of Application No. 11/804,114, thus no Decision is included in the appendix hereto.

2. There is another co-pending appeal, in Application No. 10/919,775, Appeal No. 2010-006317. Application No. 10/919,775 also claims priority to this application. No decision has yet been rendered by the Board of Patent Appeals and Interferences on the appeal of Application No. 10/919,775, thus no Decision is included in the appendix hereto.

### **III. Status of Claims**

Claims 1-9, 11-14, and 26-44 are pending.

Rejected claims: 1-9, 11-14, and 26-44

Allowed claims: none.

Withdrawn claims: none.

Objected to claims: none.

Canceled claims: 10 and 15-25

Appealed claims: 1-9, 11-14, and 26-44

#### **IV. Status of Amendments**

No amendments have been filed subsequent to the Final Rejection mailed May 24, 2010.  
All prior amendments have been entered.

## V. Summary of Claimed Subject Matter

*Note: the parenthetical citations below refer to the Applicants' specification and figures.*

Claim 1 is directed to an anastomosis device that includes a balloon, a drainage aperture, and an elongate tissue approximating structure in a certain configuration along the catheter body. Claims 2-8 and 35-38 depend from claim 1. Specifically, claim 1 recites:

1. An anastomosis device (pg. 12, l. 7-31; FIG. 4) comprising
    - a hollow, elongate, flexible catheter body (pg. 12, l. 8; ref. 42, FIG. 4) having a proximal end (pg. 12, l. 8; ref. 44, FIG. 4) and a distal end (pg. 12, l. 8; ref. 40, FIG. 4), the distal end comprising a catheter body wall,
      - an inflatable balloon (pg. 12, l. 9; ref. 48, FIG. 4) at the distal end,
      - a drainage aperture (pg. 12, l. 13; ref. 46, FIG. 4) at the distal end, and
      - elongate tissue approximating structure (pg. 12, l. 13-23; ref. 54 and 56, FIG. 4)
- that can be extended and retracted from the catheter body wall (pg. 12, l. 15-23) at the distal end of the catheter body on a proximal side of the inflatable balloon, wherein the inflatable balloon is on a proximal side of the drainage aperture (FIG. 4).

Claim 9 is directed to an anastomosis device that includes a balloon, a drainage aperture and drainage means, and an elongate tissue approximating means in a certain configuration along the catheter body. Claims 11-14 and 39-42 depend from claim 9. Specifically, claim 9 recites:

9. An anastomosis device (pg. 12, l. 7-31; FIG. 4) comprising
  - a hollow elongate flexible catheter body (pg. 12, l. 8; ref. 42, FIG. 4) having a proximal end (pg. 12, l. 8; ref. 44, FIG. 4) and a distal end (pg. 12, l. 8; ref. 40, FIG. 4), the distal end comprising a catheter body wall,
    - an inflatable balloon (pg. 12, l. 9; ref. 48, FIG. 4) at the distal end and inflation means (pg. 12, l. 10-12; ref. 50, FIG. 4) to inflate the balloon,
    - a drainage aperture (pg. 12, l. 13; ref. 46, FIG. 4) and drainage means (pg. 12, l. 12-13; ref. 52, FIG. 4) connected to the drainage aperture for draining urine from a bladder, and
    - elongate tissue approximating means (pg. 12, l. 13-23; ref. 54 and 56, FIG. 4) on the proximal side of the balloon for holding severed tissue in contact for healing (pg. 12, l. 30-31)

wherein the inflatable balloon is on a proximal side of the drainage aperture and the tissue approximating means can be extended and retracted from the catheter body wall (pg. 12, l. 15-23) at a location along the distal end of the catheter body (FIG. 4).

Claim 26 is directed to an anastomosis device that includes a drainage aperture, a first tissue approximating structure and a second elongate tissue approximating structure in a certain configuration along the catheter body. Claims 27-31 and 43-44 depend from claim 26.

Specifically, claim 26 recites:

26. An anastomosis device (pg. 12, l. 7-31; FIG. 4) comprising
- a hollow, elongate, flexible catheter body (pg. 12, l. 8; ref. 42, FIG. 4) having a proximal end (pg. 12, l. 8; ref. 44, FIG. 4) and a distal end (pg. 12, l. 8; ref. 40, FIG. 4), the distal end comprising a catheter body wall,
  - a drainage aperture (pg. 12, l. 13; ref. 46, FIG. 4) at the distal end, and
  - tissue approximating structure at the distal end of the catheter body, the tissue approximating structure comprising first tissue approximating structure (pg. 12, l. 13-17; ref. 54, FIG. 4 or, pg. 12, l. 9; ref. 48, FIG. 4) and second tissue approximating structure (pg. 12, l. 17-21; ref. 56, FIG. 4), the first and second tissue approximating structure located on a proximal side of the drainage aperture, wherein each of the first and second tissue approximating structure can be extended and retracted from the catheter body wall (pg. 12, l. 15-23; pg. 12, l. 12), and the second tissue approximating structure comprises elongate structure.

Claim 32 is directed to an anastomosis device that includes a drainage aperture, a balloon, and a tissue approximating structure that is a tine, a probe, a prod, or a needle in a certain configuration along the catheter body. Claims 33-34 depend from claim 32. Specifically, claim 32 recites:

32. An anastomosis device (pg. 12, l. 7-31; FIG. 4) comprising
- a hollow, elongate, flexible catheter body (pg. 12, l. 8; ref. 42, FIG. 4) having a proximal end (pg. 12, l. 8; ref. 44, FIG. 4) and a distal end (pg. 12, l. 8; ref. 40, FIG. 4), the distal end comprising a catheter body wall,
  - a drainage aperture (pg. 12, l. 13; ref. 46, FIG. 4) at the distal end,



an inflatable balloon (pg. 12, l. 9; ref. 48, FIG. 4) at the distal end on a proximal side of the drainage aperture,

tissue approximating structure (pg. 12, l. 13-23; ref. 54 and 56, FIG. 4) that can be extended through apertures in the catheter body wall (pg. 12, l. 15-23), at the distal end of the catheter body on a proximal side of the inflatable balloon, the tissue approximating structure comprising movable elongate structure selected from a tine, a probe, a prod, and a needle (pg. 7, l. 18-19).

**VI. Grounds of Rejection to be Reviewed on Appeal**

**A.** Whether claims 1, 2, 9, 11-12, 14, 26-29, 35, 39, and 43 are anticipated by Sharkey et al. (U.S. Patent 5,540,701).

**B.** Whether claims 3-8, 13, 30-34, 36-38, 40-42, and 44 are unpatentable over Sharkey et al. (U.S. Patent 5,540,701) in view of Kirsch et al. (U.S. Patent 6,461,367).

## VII. Argument

A. Claims 1, 2, 9, 11-12, 14, 26-29, 35, 39, and 43 are rejected under 35 U.S.C. §102(b) as being anticipated by Sharkey et al. (U.S. Patent 5,540,701).

These rejections are traversed for reasons of record and as follows.

Independent claims 1 and 9 recite an anastomosis device that includes a flexible body, an inflatable balloon at a distal end of the body, and elongate tissue approximating structure (at claim 1, or “means” at claim 9) on the proximal side of the balloon on the distal end of the body. Claim 26 contains some of the same features and differs at least by requiring not necessarily a balloon, but two tissue approximating structures, one of which is an elongate tissue approximating structure.

The prosecution of record is premised on the flawed argument that the balloon of the Sharkey reference is “elongate,” and therefore is an “elongate tissue approximating structure” as recited in certain of Applicant’s claims.

Applicant’s position of record stands, which is that that even if the broadest reasonable meaning of the term “elongate” could include the shape of the Sharkey balloon or cylinder, the claim feature of an “elongate tissue approximating structure” specifically excludes a balloon, based on the content of Applicant’s patent specification. The pending patent claims and specification use the terms “balloon” and “elongate tissue approximating structure” separately, to refer to different types of structures, which means that the claim term “elongate tissue approximating structure” excludes the separately discussed structure of a “balloon,” and vice-versa. Applicant’s specification’s consistent and uniform use of the two different terms “balloon” and “elongate tissue approximating structure” to define two different types of “tissue approximating structures” means that the term “balloon” is outside of the meaning of “elongate tissue approximating structure.”

*a. According to the application a “balloon” structure is a different than an “elongate tissue approximating structure”*

The application identifies two specific types or embodiments of “tissue approximating structures”: 1) balloons and 2) “elongate tissue approximating structure.” The application consistently treats these two different types of tissue approximating structures separately, as

different structures. For example, paragraph [0030] includes the following discussion of these two different types of “tissue approximating structures” (emphasis added):

*The tissue approximating structure may include, for example, one or multiple balloon or balloon-like structures that can be placed against the inside of the bladder or underneath the perineal floor to bring the severed bladder neck tissue into contact with the severed tissue surface of the urethral stump. Alternatively, the tissue approximating structure may include elongate structures such as a needle, tine, prod, probe, or the like, which may have a blunt or a sharp end and may movably extend or protrude from an aperture in a flexible catheter body at a location where the structure can function as an approximating structure, e.g., at the distal end of the device where the structure will be near the bladder or perineal wall (when installed), or at a severed urethra below the perineal floor (when installed). Combinations of balloons and elongate structures may also be useful in certain applications.* (Emphasis added.)

Here and throughout the application the inclusive term “tissue approximating structure” is used broadly to include two different species of the generic term “tissue approximating structure”: one type is a “balloon” and the other is the type of non-balloon structures referred to as “elongate tissue approximating structures.” Repeatedly and consistently the term “balloon” refers to a tissue approximating structure that is an alternative to (i.e., different from) an “elongate tissue approximating structure.” Likewise, the term “elongated tissue approximating structure” is used repeatedly and consistently in a manner to exclude a “balloon” from its meaning. The distinction between these two different types of “tissue approximating structures” is made repeatedly and uniformly. For example, see also paragraphs [0035] and [0036], again consistently indicating that “tissue approximating structures” generally include at least these specific two types, which are different structures:

*Exemplary tissue approximating structure may be in the form of a rigid elongate structure that moves from a retracted position (e.g., inside of the catheter body) to an extended position through apertures in the catheter body, such as a movable, elongate, tine or needle type structure. Such a tine or needle structure may include a pointed end to penetrate into or through a tissue. Exemplary elongate structures can be positioned to movably engage apertures in the catheter wall through which the elongate structures can be extended or retracted. Optionally, a guide such as a metal, ceramic, rigid plastic, or polymeric guide can be placed at the aperture between the catheter body wall and the movable elongate structure.*

*Alternatively, the tissue approximating structure may include one or two balloons that can be positioned to cause contact of two opposing severed tissue surfaces. For example, two balloons may be located to contact the opposite sides of a bladder wall and a perineal floor, one balloon in the bladder and the other below the perineal floor, at a*

*spacing that maintains contact between a severed bladder neck tissue and a severed urethral stump.*

(Emphasis added.) Likewise, similar identifications of “elongate tissue approximating structure,” different from a “balloon” as a tissue approximating structure, are found at published claims 32 and 33:

*32. The method of claim 31 wherein the first tissue approximating structure is selected from the group consisting of a balloon and a balloon-like structure.*

*33. The method of claim 31 wherein the second tissue approximating structure comprises movable elongate structure selected from a tine, a probe, a prod, and a needle.*

Throughout the entire application, as in claim 33, examples of “elongate tissue approximating structure” include specific known “elongate” structures such as a “tines, a probe, a prod, and a needle,” none of which is a balloon structure, a spherical structure, or other any other “balloon-like” structure.

Any objective reader would read the pending application as using the term “elongate tissue approximating structure” to refer to various structures, none of which is a balloon. Correspondingly, and consistently, the reader would recognize that the term “balloon” is used for structures that are not “elongate tissue approximating structure” but that are structures understood to be “balloons.”

Based on Applicant’s consistent and uniform description of different “tissue approximating structures” in their application, including “elongate tissue approximating structure” different from a “balloon,” these terms are distinct and not overlapping, and the term “elongate tissue approximating structure” in the pending claims does not include a balloon.

*b. The MPEP and caselaw precedent require that the feature “elongate tissue approximating structure” construed in view of Applicant’s specification does not read on the Sharkey balloon*

According to the MPEP and unwavering caselaw precedent, a patent claim during examination is construed in view of the patent’s specification. The meaning given to claim terms is the “broadest reasonable interpretation consistent with the specification.” From the MPEP, at section 2111:

*2111 Claim Interpretation; Broadest Reasonable Interpretation*

*During patent examination, the pending claims must be 'given their broadest reasonable interpretation consistent with the specification.'* >The Federal Circuit's en banc decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard:

*The Patent and Trademark Office ('PTO') determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction 'in light of the specification as it would be interpreted by one of ordinary skill in the art.'* In re Am. Acad. of Sci. Tech. Ctr., 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004). Indeed, the rules of the PTO require that application claims must 'conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.' 37 CFR 1.75(d)(1). (Emphasis added.)

As explained hereinabove, the meaning of the phrase "elongate tissue approximating structure" - even its broadest reasonable meaning -- does not cover a two-dimensional exterior surface area of a balloon, which, being dimensioned as a surface area, is not "elongate." On that ground alone the rejection should be withdrawn or overturned. But more decisively, even if the meaning of "elongate tissue approximating structure" were generally (i.e., outside the context of the pending patent application) capable of reading on a two-dimensional surface of a balloon, Applicant's specification expressly indicates that "tissue approximating structures" can be in the form of a "balloon," or on the form of a non-balloon, "elongate tissue approximating structure." Expressly or implicitly the claim term "elongate tissue approximating structure" excludes the alternate type of "tissue approximating structure," a balloon.

The Court of Appeals for the Federal Circuit has held that during examination a claim term is given meaning by the patent specification. As opposed to improperly reading an unstated claim feature into a claim, a term that expressly appears in a claim must be given a meaning consistent with the patent specification. The meaning must (not optionally) take into account "definitions" or "whatever enlightenment" are found in the specification to give Applicant's intended meaning to the claim term:

*[The] PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise*

that may be afforded by the written description contained in applicant's specification.<sup>1</sup>  
(Emphasis added.)

Accordingly, a patent claim term is construed during examination in a manner dictated by the patent's specification. At present, Applicant's specification consistently and uniformly uses the term "balloon" to refer to one specific type of "tissue approximating structure" that is different than and alternative to "elongate tissue approximating structure." The specification similarly uses the alternate term "elongate tissue approximating structure" to refer to tissue approximating structure that is different from and alternate to a "balloon." These terms have different meanings in the specification, and those different meanings must be respected during examination. As a consequence the term "elongate tissue approximating structure" must be construed to not include the separately and differently described alternate "tissue approximating structure" of a "balloon."

The outstanding rejections, especially as articulated in the Advisory Action, are premised on the flawed argument that an "elongate tissue approximating structure" of independent claims 1 and 9, and the "second tissue approximating structure compris[ing] elongate structure" at claim 26, identically read on the balloon of Sharkey. In view of the specification, the claimed "elongate tissue approximating structure" and "elongate structure" exclude a "balloon" structure (which is an alternate form of "tissue approximating structure"). The premise of the rejection is refuted and the rejection cannot be sustained. The rejection of claims 1, 9, 26, and their dependent claims should be withdrawn.

**B.** Claims 3-8, 13, 30-34, 36-38, 40-42, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharkey et al. (U.S. Patent 5,540,701) in view of Kirsch et al. (U.S. Patent 6,461,367).

These claims depend on independent claim 1, 9, or 26, and, therefore, require the tissue approximating structure features of those independent claims, including at least one "elongate" tissue approximating structure.

The grounds of rejection of record are traversed.

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<sup>1</sup> *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997).

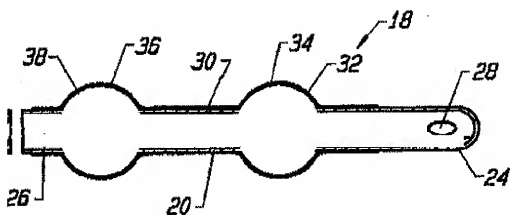
In sum, no rejection of record has identified any legally sound reason why one of skill would have replaced the balloon of Sharkey with the tines of Kirsch, where the offered reasoning is based on information found in the cited prior art references taken as a whole and without the benefit of Applicant's own disclosure.

The patent laws require that a prior art reference used to reject a claim be "taken as a whole." When citing a reference that describes a device designed for use in a specialized method of treatment, the device and each one of its constituent parts must be understood to exist in the context of that specialized method of treatment. The structure of a device cannot be arbitrarily divorced from the method that the device is specifically designed to perform; and any individual structural component of the device required to provide a particular (even singular) function, cannot be considered in the absence of its function. A rejection, in considering such a prior art reference "as a whole" must respect the function of each structure of such a device and the purpose for which the structure is present on the device, the existential purpose of the structure as part of the prior art device for performing its intended specialized prior art method.

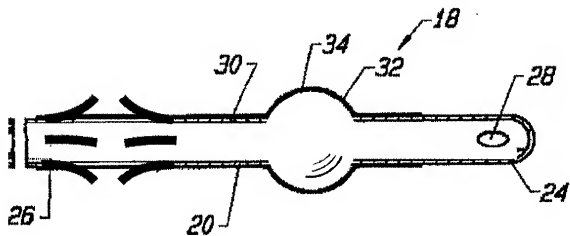
In view of these legal requirements, one of skill would not have removed the balloon 36 from the Sharkey device and replaced the balloon with "prongs" from the Kirsch reference. Neither the Sharkey nor the Kirsch reference recognizes any utility for a device that would result from the rejection's proposed structural modification to produce a catheter body comprising two structures, one a distal balloon and the second being an "elongate tissue approximating structure" in the form of a "a tine, a probe, a prod, [or] a needle." (Or, at claim 5, elongate tissue approximating structure positioned to extend "through apertures in the hollow catheter body." The rejection does not ever mention or consider this feature of claim 5. Therefore, upon reconsideration of claim 5 in particular, for this additional reason, the rejection of claim 5 should be withdrawn.)

The Sharkey device requires two balloons, 32 and 36 (or balloon-like equivalent structures), each of which functions to expand helical structure 12 or 14:

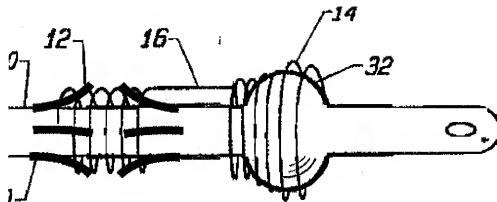




A device according to the proposed rejection would necessarily remove balloon 36 from the device. The removed balloon would be replace by "everting prongs" of Kirsch:



When assembled to perform the method of Sharkey, to install a fixation device 10, the device takes on this form.



Plainly this proposed device would not provide the utility required of the Sharkey device: to perform the Sharkey method of installing fixation device 10. Consequently one of skill would not have made the modification proposed in the outstanding rejections.

The Sharkey reference describes catheter 18 useful to install fixation device 10. The Sharkey balloon 36 functions to expand helical structure 12 of fixation device 10 by producing an expanding balloon surface area that pressures and expands the helical structure 12. See figures 12 and 13 of Sharkey. The structure of the balloon must include an expanding surface area (or the equivalent) that can contact the inside region of a helical structure 12 of the device and expand to cause the helical structure to expand outwardly. This is required, to install fixation device 10.

Undeniably, the tines of Kirsch would not perform the function of the Sharkey balloon; and with this point no rejection of record disagrees, meaning that the rejections at least implicitly agree. Because these everting prongs would not perform the function of the Sharkey balloon, there is no sensible (e.g., useful, functional) reason to remove the Sharkey balloon and replace the balloon with “prongs.” The rejection proposes to remove the balloon structure (36) that is perfectly suited and useful to perform the specialized function of expanding helical structure 12, in favor of a different structure (everting prongs) that would not perform that specialized (and required by the Sharkey device) function.

The assertion that one of skill would have removed a balloon useful to perform a needed device function, to replace the balloon with prongs not so useful, entirely ignores the sole and exclusive purpose of the Sharkey device, which is to install fixation device 10. The device has no other useful purpose. And without the balloon or an equivalent structure capable of

expanding helical structure 12, the Sharkey device becomes incapable of performing that sole useful purpose. The modified Sharkey device would be inoperable for any function contemplated by the Sharkey reference.

The recent Advisory Action states the following rationale for why one of skill supposedly would have removed the Sharkey balloon and replaced that functional structure with the “everting prongs” of Kirsch:

*... it would have been obvious . . . to replace the (second) tissue approximating structure of Sharkey et al. with one that comprises multiple distal and proximal opposing tines . . . as taught by Kirsch et al. in order to facilitate the approximation of tissue portions by anchoring the urethral stump and bladder neck with tines to ensure proper connection between the urethra and bladder . . . , as well as to selectively approximate tissue when desired.*

This passage asserts two supposed reasons for why one of skill would have removed the Sharkey balloon and placed the Kirsch prongs at the balloon’s location on the Sharkey device: the first involves “anchoring the urethral stump and bladder neck with tines,” and the second is “to selectively approximate tissue when desired.”

a. *One of skill would not have removed the Sharkey balloon to replace that functionally-required feature of catheter 18 with distal and proximal opposing tines, to use the opposing tines to “selectively approximate tissue when desired.”*

Addressing the second item first, the skilled artisan starting with information in the Sharkey and Kirsch references would not have removed the second Sharkey balloon (36) from the Sharkey catheter device 18 and replaced that balloon with multiple distal and proximal opposing prongs, so the opposing prongs could be available to “selectively approximate tissue when desired.”

The reason is obvious and mentioned above: the Sharkey device cannot perform its sole intended purpose (of installing fixation device 10) without balloon 36 or some equivalent structure able to perform the function of balloon 36. Removing balloon 36 from catheter 18 and replacing the balloon with opposing tines that are incapable of functioning to expand helical structure 12 causes the entire catheter device 18 to be incapable of performing its sole function of delivering fixation device 10 to a body lumen. Because the resultant device 18 would be non-functional, i.e., inoperative for its sole intended purpose, one of skill would not have made the replacement proposed by the rejection, and this ground of rejection fails.

- b. One of skill would not have removed the Sharkey balloon 36 and replaced that feature of the Sharkey catheter 18 with distal and proximal opposing tines for the purpose of "facilitat[ing] the approximation of tissue portions by anchoring the urethral stump and bladder neck with tines to ensure proper connection between the urethra and bladder."

As for the second rationale, it too is inconsistent with the needed functionality of the Sharkey device, because this reason also requires that the balloon be removed from the Sharkey device, which would cause the device to be non-functional for its sole intended purpose.

This second rationale additionally lacks validity because it incorrectly states that tissue "anchoring" can be performed "with tines." That is, the rejection incorrectly proposes that the Kirsch reference either shows or suggests the use of the Kirsch "everting prongs" for "anchoring" tissue, which it does not.

The Kirsch device does not use opposing prongs to anchor bladder and urethral tissue. Instead, the reference on multiple occasions expressly states the requirement that a step of "securing the urethra to the bladder" be performed using a "clip" or other unspecified securing structure different from the "everting prongs." The Kirsch reference does not ever indicate that this "securing" (i.e., anchoring) step can be performed using the described "prongs."

When the urethral tissue and the bladder tissue are in close proximity, the urethra and the bladder are reconnected using at least one clip. The urethra is secured to the bladder

Kirsch at column 1, lines 62-65 (emphasis added).

The method further comprises the step of advancing the second approximation device toward the first approximation device so that a distal end of the urethra comes in close proximity to a distal end of the bladder. The final step of the method comprises securing the urethra to the bladder.

Kirsch at column 2, lines 5-10 (emphasis added).

The method further comprises advancing the first approximation device and the second approximation device toward one another so that a distal end of the urethra comes in close proximity to a distal end of the bladder. Finally, the urethra is secured to the bladder.

Kirsch at column 2, lines 17-21 (emphasis added).

The prong secures the second approximation device to the bladder. The system further comprises at least one clip. The clip is suitable to secure the urethra to the bladder once the urethra and bladder are within close proximity.

Kirsch at column 2, lines 32-37 (emphasis added).

The Kirsch reference consistently describes the use of “prongs” not to “anchor” or “secure” tissue but to engage tissue for a separate “securing” mechanism such as a clip. See also column 4, lines 19-34:

*When the trocar 16 and the sheath 24 meet, the tapered distal end 20 of the trocar 16 enters the cavity 34 in the distal end 32 of the sheath 24, to an extent sufficient to enable the urethral tissue and the bladder tissue to press together as shown. Fit together in this manner, the trocar 16 and the sheath 24 can retain the tissues in this orientation suitable for the connection process, in a “hands-free” manner. The tissues of the urethra 10 and the bladder 12 are subsequently clamped together using one or more external clips 38, around the circumference of the urethra-bladder attachment. The application of the clips may effect disengagement of the bladder tissue 12 from the everting prongs 30. In one embodiment, VCS clips are used to secure the urethral tissue to the bladder. The clips 38 may be applied either individually, or simultaneously in a “one-shot” fashion.*

Plainly the assertion that the Kirsch reference describes the possibility of securing or “anchoring” a urethral stump and bladder neck “with tines” is not based on information found in the Kirsch reference. The idea that “tines,” “prongs,” or “elongate tissue approximating structure” may be used to hold or secure tissue together for healing is found only in Applicant’s patent application, not in either cited prior art reference, and has not been otherwise shown to be part of the prior art before Applicant’s invention.

In sum, based on the information and knowledge that can be shown to be derived from the Kirsch and Sharkey references, one of skill would not have removed the balloon from the Sharkey device and replaced the balloon with a structure that does not perform the function of the balloon (e.g., elongate everting “prongs”). Elongate prongs would not possibly function to expand helical structure 12, and the Sharkey device 18 would be non-functioning for its intended purpose. Additionally, the information of the Kirsch reference does not show that prior to Applicant’s invention “everting prongs” were known to be used or useful for “anchoring the urethral stump and bladder neck.” The Kirsch reference describes using “clips” to secure these tissues together. Thus, that reasoning of the rejection is also not supported by the Kirsch reference.

**Conclusion**

In view of these remarks, it is respectfully submitted that pending claims 1-9, 11-14, and 26-44 are in condition for allowance. Accordingly, it is respectfully submitted that the rejections of the claims under 35 U.S.C §§ 102 and 103 be withdrawn on this appeal.

Respectfully Submitted,

Dated: Dec 22, 2010

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### **VIII. Appendix – Claims on Appeal**

1. An anastomosis device comprising
  - a hollow, elongate, flexible catheter body having a proximal end and a distal end,
  - the distal end comprising a catheter body wall,
  - an inflatable balloon at the distal end,
  - a drainage aperture at the distal end, and
  - elongate tissue approximating structure that can be extended and retracted from the catheter body wall at the distal end of the catheter body on a proximal side of the inflatable balloon,wherein the inflatable balloon is on a proximal side of the drainage aperture.
2. The device of claim 1 wherein, when the device is installed in a body having a prostate removed, with the balloon in the bladder, the tissue approximating structure is capable of contacting tissue selected from tissue of a bladder, tissue of a perineal wall, urethral tissue, and combinations of these.
3. The device of claim 1 wherein the tissue approximating structure comprises movable elongate structure selected from a tine, a probe, a prod, and a needle.
4. The device of claim 3 wherein the tissue approximating structure can be extended and retracted from apertures in the catheter body using an actuating mechanism that extends through a lumen along a portion of the length of the device to the proximal end.
5. The device of claim 1, comprising
  - an inflation lumen extending from the proximal end to the balloon,
  - a drainage lumen extending from the drainage aperture at the distal end to a port at the proximal end, and
  - movable elongate tissue approximating structure positioned to extend through apertures in the hollow catheter body at the distal end.

6. The device of claim 1, comprising
  - an inflation lumen extending from the proximal end to the balloon,
  - a drainage lumen extending from the drainage aperture at the distal end to a port at the proximal end, andwherein the tissue approximating structure comprises
  - distal tissue approximating structure comprising movable elongate tines positioned to extend through apertures in the hollow catheter body on the proximal side of the balloon, and
  - proximal tissue approximating structure comprising movable elongate tines positioned to extend through apertures in the hollow catheter body on the proximal side of the distal tissue approximating structure.
7. The device of claim 1 wherein the tissue approximating structure comprises multiple tines.
8. The device of claim 1 wherein the tissue approximating structure comprises multiple opposing tines.
9. An anastomosis device comprising
  - a hollow elongate flexible catheter body having a proximal end and a distal end, the distal end comprising a catheter body wall,
  - an inflatable balloon at the distal end and inflation means to inflate the balloon,
  - a drainage aperture and drainage means connected to the drainage aperture for draining urine from a bladder, and
  - elongate tissue approximating means on the proximal side of the balloon for holding severed tissue in contact for healingwherein the inflatable balloon is on a proximal side of the drainage aperture and the tissue approximating means can be extended and retracted from the catheter body wall at a location along the distal end of the catheter body.
10. (canceled)



11. The device of claim 9 further comprising actuating means for actuating the tissue approximating means, the actuating means connected to the tissue approximating means and extending from the tissue approximating means to the proximal end.
12. The device of claim 9 wherein the tissue approximating means is selected from the group consisting of an inflatable balloon, a movable elongate structure, and a combination thereof.
13. The device of claim 9 wherein the tissue approximating means comprises a movable tine.
14. The device of claim 9 wherein, with the device positioned to place the at least a portion of the catheter body inside the urethra and the inflated balloon in the bladder, the tissue approximating means can be extended to contact tissue selected from the group consisting of bladder tissue, urethral tissue, urethral stump tissue, and perineal wall tissue.
- 15-25. (canceled)
26. An anastomosis device comprising
  - a hollow, elongate, flexible catheter body having a proximal end and a distal end, the distal end comprising a catheter body wall,
  - a drainage aperture at the distal end, and
  - tissue approximating structure at the distal end of the catheter body, the tissue approximating structure comprising first tissue approximating structure and second tissue approximating structure, the first and second tissue approximating structure located on a proximal side of the drainage aperture, wherein each of the first and second tissue approximating structure can be extended and retracted from the catheter body wall, and the second tissue approximating structure comprises elongate structure.
27. The device of claim 26 wherein, when the device is positioned to place a distal portion of the catheter body inside the urethra, the first tissue approximating structure can be located to contact tissue of the bladder and the second tissue approximating structure is located to contact

tissue selected from tissue of a bladder, tissue of a perineal wall, urethral stump tissue, tissue inside a urethra and combinations of these.

28. The device of claim 27 wherein the first tissue approximating structure is selected from the group consisting of a balloon and a balloon-like structure.

29. The device of claim 28 wherein the first tissue approximating structure, when placed inside of the bladder, is capable of expanding within the bladder to prevent urine from passing through the bladder neck and urethra to an anastomosis site.

30. The device of claim 27 wherein the second tissue approximating structure is located on a proximal side of the first tissue approximating structure, and the second tissue approximating structure comprises movable elongate structure selected from a tine, a probe, a prod, and a needle.

31. The device of claim 30 wherein the second tissue approximating structure comprises multiple opposing tines.

32. An anastomosis device comprising  
a hollow, elongate, flexible catheter body having a proximal end and a distal end,  
the distal end comprising a catheter body wall,  
a drainage aperture at the distal end,  
an inflatable balloon at the distal end on a proximal side of the drainage aperture,  
tissue approximating structure that can be extended through apertures in the  
catheter body wall, at the distal end of the catheter body on a proximal side of the inflatable  
balloon, the tissue approximating structure comprising movable elongate structure selected from  
a tine, a probe, a prod, and a needle.

33. The device of claim 32 wherein the tissue approximating structure can be extended and retracted through the apertures in the catheter body using an actuating mechanism that extends through a lumen along a portion of the length of the device to the proximal end.

34. The device of claim 32 comprising

distal tissue approximating structure comprising movable elongate tines positioned to extend through apertures in the hollow catheter body on the proximal side of the balloon, and

proximal tissue approximating structure comprising movable elongate tines positioned to extend through apertures in the hollow catheter body on the proximal side of the distal tissue approximating structure, wherein the distal tissue approximating structure can be extended and retracted through the apertures in the catheter body using an actuating mechanism that extends through a lumen along a portion of the length of the device to the proximal end, and wherein the proximal tissue approximating structure can be extended and retracted through the apertures in the catheter body using an actuating mechanism that extends through a lumen along a portion of the length of the device to the proximal end.

35. The device of claim 1 wherein tissue approximating structure can be extended and retracted from the catheter body wall at a fixed location on the catheter body, the fixed location being fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body, and wherein the balloon can be extended and retracted from the catheter body wall at a fixed location on the catheter body, the fixed location being fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body.

36. The device of claim 35 wherein the tissue approximating structure comprises multiple tines.

37. The device of claim 1 wherein the tissue approximating structure comprises distal tissue approximating structure comprising multiple tines, and proximal tissue approximating structure comprising multiple tines that oppose the multiple tines of the distal tissue approximating structure,

wherein the distal tissue approximating structure can be extended and retracted from the catheter body wall at a fixed location on the catheter body, the fixed location being fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body, and the proximal tissue approximating structure can be extended and retracted from the catheter body wall at a fixed location on the catheter body, the fixed location being fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body.

38. The device of claim 37 wherein the position of the balloon on the catheter body is fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body.

39. The device of claim 9 wherein tissue approximating means can be extended and retracted from the catheter body wall at a fixed location along the distal end of the catheter body, the fixed location being fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body.

40. The device of claim 39 wherein the tissue approximating means comprises multiple tines.

41. The device of claim 9 wherein tissue approximating means comprises  
distal tissue approximating means comprising multiple tines, and  
proximal tissue approximating means comprising multiple tines that oppose the multiple tines of the distal tissue approximating means,  
wherein the distal tissue approximating structure can be extended and retracted from the catheter body wall at a fixed location on the catheter body, the fixed location being fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body, and the proximal tissue approximating structure can be extended and retracted from the catheter body wall at a fixed location on the catheter body, the fixed location being fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body.

42. The device of claim 41 wherein the position of the balloon on the catheter body is fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body.

43. The device of claim 26 wherein the first approximating structure can be extended and retracted from the catheter body wall at a fixed location on the catheter body, the fixed location being fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body, and

the second tissue approximating structure can be extended and retracted from the catheter body wall at a fixed location on the catheter body, the fixed location being fixed relative to the distal end of the catheter body and relative to the proximal end of the catheter body.

44. The device of claim 43 wherein the first tissue approximating structure comprises an inflatable balloon and the second tissue approximating structure comprises multiple tines.

## **IX. Appendix - Evidence**

There is no evidence to be included.

**X. Appendix - Related Proceedings**

There are no Decisions related to the two related appeals cited at page 4.